APR 8 2005

510(k) Summary of Safety & Effectiveness

K043253/S2

Submitter

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Contact

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Date

November 23, 2004

Device

- Trade Name: Vanguard Reprocessed Dilating Tip and Blunt Trocars
- Common Name: Dilating tip/shielded trocar, Blunt/non-shielded trocar, Adjustable stability thread
- Classification Number: 21 CFR 876.1500
- Classification Name: Endoscope and accessories
- Product Code: NLM – Laparoscope, General & Plastic Surgery, Reprocessed – Class II

Predicate Devices

Original equipment manufacturer (OEM) Dilating Tip and Blunt Trocars are currently marketed under a variety of trade names. Trade names of legally marketed predicate devices are:

- Ethicon® Tristar™ Blunt Tip Trocar (10mm-12mm)
- Ethicon® Endopath® Dilating Tip Trocar (5mm-12mm)
- Ethicon® Endopath® Optiview® Optical Trocar (5mm-12mm)
- Ethicon® Tristar™ Pyramidal Blade Trocar (5mm-12mm)
- Ethicon® Endopath® Adjustable Stability Thread (5mm-12mm)

The 510(k) Premarket Notification numbers for these devices are:

- K020428: Endopath® Dilating Tip Trocar
- K011538: Endopath® Non-Bladed Solid Obturator Trocar System
- K011257: Endopath® Non-Bladed Obturator Trocar System (5mm)
- K990028: Endopath® Optiview® Optical Surgical Obturator and Sleeve
- K971475: Shielded Surgical Trocar
- K963760: Non-Shielded Surgical Trocar and Sleeve

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510(k) Summary of Safety & Effectiveness, Continued

Indications for Use

Reprocessed trocars are intended to provide a pathway for entry of instruments during minimally invasive surgery, with particular applications in abdominal, gynecological, urological, and thoracic procedures.

Contra-indications

Reprocessed trocars should not be used in patients for whom endoscopic procedure is contraindicated.

Device Description

Vanguard Reprocessed Trocar is a previously used device that has been cleaned, inspected, packaged and sterilized by Vanguard Medical Concepts, Inc.

Trocar Cannulae is available with smooth or threaded sleeve in sizes 5-15mm inner diameter and 5-15cm length. Cannulae are equipped with a pressure seal for maintenance of pneumopertineum during insertion and withdrawal of instruments. Some models are equipped with a luer stopcock port for insufflation and desufflation of the operative cavity. Some models are provided with stability anchors inserted over the cannula sleeve to help seal the incision site and maintain cavity pressure.

Trocar Obturator is available in shielded and non-shielded configurations sized 5-15mm. Models equipped with a safety shield are designed to expose the blade during insertion but to retract over the tip once the operative cavity has been penetrated, so as to reduce the risk for vascular or visceral injury. Non-shielded optical obturators are equipped with a clear tip and an 11-12mm video laparoscopy channel to allow trocar insertion under direct visual guidance and minimize the risk for internal injury.

Technological Characteristics

Vanguard Reprocessed Dilating and Blunt Tip Trocars are essentially identical to the Original Equipment Manufacturer (i.e., Ethicon®) devices. No changes are made to the device materials or specifications and the reprocessed trocars possess identical technological characteristics.

Test Data

Cleaning, sterilization, packaging validations, and performance and biocompatibility testing demonstrate that the reprocessed devices perform as intended and are safe and effective.

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Conclusion

Based upon the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that Vanguard Reprocessed Dilating Tip and Blunt Trocars are substantially equivalent to their predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 8 2005

Ms. Heather Crawford, RAC
Director of Regulatory Affairs
Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, Florida 33815

Re: K043253
Trade/Device Name: Vanguard Reprocessed Dilating Tip and Blunt Trocars
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NLM
Dated: March 15, 2005
Received: March 24, 2005

Dear Ms. Crawford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043253

Device Name: Vanguard Reprocessed Dilating Tip and Blunt Trocars

Indications for Use:

Reprocessed Trocars are intended to provide a pathway for entry of instruments during minimally invasive surgery, with particular applications in abdominal, gynecological, urological, and thoracic procedures.

Prescription Use__X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, Restorative and Neurological Devices
K043253